REMARKS

I. Status of Claims.

This application has been reviewed in light of the Office Action dated July 21, 2003. Claims 1-16 are presently pending. Claims 4 and 11 have been amended in a manner that is believed to overcome rejections contained in the pending Office Action. The amendments to claims 4 and 11 were made to more specifically define Applicants' invention and not for reasons of prior art. No new matter or issues are believed to be introduced by these amendments. Support for the amendments can be found throughout the specification, the claims as originally filed and the drawings.

II. Objection to Oath or Declaration.

The Examiner in the office action dated June 13, 2002 objected to the oath or declaration as not being in compliance with 37 CFR 1.67 (a). Examiner again makes note of the defective Oath or Declaration. Applicants submitted a new oath and declaration in compliance with 37 CFR 1.67 (a), on January 13, 2003. The Examiner objected to this newly submitted oath and declaration as containing non-initialed and/or non-dated alterations. Applicants have made note of these objections and will submit a new oath and declaration in compliance with 37 CRF 1.67 (a) upon receipt thereof from the inventors.

III. Information Disclosure Statement.

The Examiner objected to those references within the Information Disclosure Statement (IDS) filed on January 13, 2003 without English translations. Applicants have attached to this response translations of those foreign references for further consideration by the Examiner.

A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:

> **GERMAN LANGUAGE EP 0 995 440 A1:** Apparently relates to a method of raising the blood sugar level in a mammal having hypoglycemia is described. The method reduces degradation of glucagon by administering to the mammal a therapeutically effective amount of an inhibitor of dipeptidyl peptidase IV and physiologically acceptable adjuvants and/or excipients.
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> **JAPANESE LANGUAGE JP 0 428 8098:** Apparently relates to a novel peptide inhibiting a dipeptidyl carboxypeptidase having a vosopressor activity, ordinarily added to foods to normally maintain the blood pressure of a body without causing adverse actions even when continuously taken in the body.

V. Claims 9-13 and 15 rejected under 35 USC 112 first paragraph.

The Examiner rejected claims 9-13 and 15 under 35 USC 112, first paragraph stating that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make an/or use the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

A. Examiner's Rejection: The Examiner stated that the specification only discloses cursory conclusions without data supporting the findings, which state that the compounds of unstable inhibitors of DP IV can be used for the treatment of disorders in mammals by modulating the DP IV enzymatic activity, especially metabolic disorders associated with diabetes mellitus. The Examiner further stated that "[t]here are no indicia that the present application enables the claimed methods in view of treating a metabolic disorder in mammals as discussed in

the stated rejection and that the present application provides no indicia and no teaching/guidance as to how the claimed methods are enabled." Applicants respectfully traverse this rejection.

B. Requirements of Written Description: Applicants respectfully suggest that under the provision of 35 USC 112, first paragraph it is not required that Applicants demonstrate the use of a compound. The written description requirements generally require Applicants to provide an enabling description of the invention sufficient for one of ordinary skill in the art. The CCPA has stated that "[n]ot every last detail is to be described, else patent specification would turn into production specifications, which they were never intended to be." In re Gay, 309 F.2d 769, 135 USPQ 311, 316 (C.C.P.A. 1962). Applicants must merely provide sufficient detailed as to allow a person skilled in the art the ability to practice the invention. This they have done.

It is further respectfully noted that Applicants are not required to convince. In the absence of evidence or apparent reason why the invention does not perform as claimed, the allegation of enablement in the Specification must be accepted as correct. See, In re Bundy, 209 U.S.P.Q. 48 (CCPA 1981) (addressing utility).

C. Efficacy need not be proven: In the Office action of July 21, 2003, the Examiner stated that "the specification only indicates the amount of the inhibitor for inhibiting DP IV *in vivo* is different in individual cases, and the compound in the pharmaceutical composition can be used for treatment of metabolic disorders by modulating the DP IV activity, the specification does not provide sufficient guidance and teaching on treating conditions such as effective doses used for treating metabolic disorder, nor indicates the effect of the inhibitor in the treatment." As stated by the court in Carter-Wallace, this is an improper basis for rejection:

> There is nothing in the patent statute or any other statutes called to our attention which gives the Patent Office the right or duty to require an applicant to prove that compounds or other materials which he is claiming, and which he had stated are useful for 'pharmaceutical applications' are safe, effective, and reliable for humans. See Carter-Wallace, Inc. v. Riverton Labs., 167 U.S.P.Q. 656, 660-61 (2d. Cir. 1970)

Insofar as the rejection is based on the absence of proof of effectiveness the rejection is speculative and improper. Applicants must merely disclose that which is necessary to enable one skilled in the art. This they have done. Instructive guidance in determining the level of ordinary skill has been provided by the Federal Circuit as follows:

> "The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative. Factors that may be considered in determining level of skill include; type of problems encountered in art; prior art solutions to those problems. Rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." Custom Accessories Inc. V. Jeffrey-Allan Indus., 807 F.2d 955, 1 U.S.P.Q. 2d 1196, 1201 (Fed. Cir. 1986).

It is settled law that a specification, drawn to one of ordinary skill in the art, need only describe enough information to allow one of ordinary skill in the art to make the invention work. Ex parte Naujoks, 17 U.S.P.Q.2d 1537, 1540 (PBAI 1989). Applicants respectfully note that the first paragraph of Section 112 requires nothing more than objective enablement. This is achieved by the use of illustrative examples or by broad terminology. *In re* Marzocchi, 169 USPQ 367 (C.C.P.A. 1971). It is respectfully submitted that the existence and identity of DP IV inhibitors are known to those of skill in the art, and having been cited are enabled. Accordingly, Applicants respectfully submit that the breadth of the Claims 9 and 11 are clearly enabled by the instant specification, and Claims 10, 12-13 and 15 dependent thereon.

The Examiner additionally states that Applicants have not indicated the treating conditions such as the dose, method of administration and the effect of the compound. Applicants would respectfully suggest that it has disclosed within the specification a method of administration. (see specification page 5 line 5-7), dosing (see specification page 8 line 32-33; page 9 line 14-18) and the effect of the compound (see specification page 5 lines 8-11). Claim language must be read in light of the specification as it would be interpreted by one of ordinary

skill in the art. In re Moore, 58 CCPA 1042, 1046-1047, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (1971). Applicants respectfully submit that they have more than met the requirements of 35 USC 112 for claims 9-13 and 15 and would therefore respectfully request that this rejection be withdrawn.

VI. Rejection of claims 4, 11-13 and 15 rejected under 35 USC 112, second paragraph.

A. Examiner's rejection of claim 4: The Examiner rejected claim 4 under 35 USC 112 , second paragraph because it is not clear what the terms "Thia" and "Pyr" mean. Applicants would respectfully submit that in accordance with conventional terminology understood by those skilled in the art "Thia" denotes "thiazolidine", which is a mimetic of the amino acid proline and "Pyr" denotes pyrrolidine. In response the Examiner's criticism on this, Applicants have amended claim 4 to include the full chemical name of these compounds. Applicants would respectfully submit that with the amendments to claim 4 this rejection has been overcome.

B. Examiner's rejection of claims 11-13 and 15: Further rejection under 35 USC 112, second paragraph was made regarding claims 11-13 and 15. The Examiner stated that the claims as presented lack the omitted steps of the effective amount of the compound used and the method of administration and the outcome for the treatment. Applicants previously amended claim 11 to more clearly define the claimed method requiring that a therapeutically effective amount of the compound be administered. The Examiner stated that the claim only cites administration of "a therapeutically effective amount of the compound" but without recitation of the endpoint of the treatment, thus it is not clear what the effective amount of the compound would do. Applicants have responsively amended claim 11 from which claims 12-13 and 15 depend to further emphasize that the "therapeutically effective amount" reduces elevated blood glucose.

The amendment to claim 11 emphasizes an endpoint of treatment as the Examiner has requested. The inclusion of this endpoint allows one skilled in the art to determine the specific valves for a "therapeutically effective amount". While the phrase "an effective amount" or as in this instant case "a therapeutically effective amount" may raise the issue of indefiniteness, the appropriate test is whether one skilled in the art could determine the specific values for the amount required to be "effective" based on the application disclosure and the prior art. See In re Mattison, 509 F.2d 563, 184 USPQ 484, 486 (C.C.P.A. 1975). Applicants respectfully submit that the amendment to claim 11 satisfies the principles of Mattison and overcomes the rejection as to 35 USC 112, second paragraph. Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

Applicants respectfully request expeditious consideration and passage of the present application to issuance. The Examiner is invited and encouraged to telephone the undersigned if she believes such would facilitate prosecution of the present application.

Respectfully submitted,

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